Package leaflet: Information for the user

Spikevax 0.2 mg/mL dispersion for injection
Spikevax 0.1 mg/mL dispersion for injection
Spikevax 50 micrograms dispersion for injection in pre-filled syringe
COVID-19 mRNA Vaccine (nucleoside modified)
elasomeran

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Spikevax is and what it is used for

Spikevax is a vaccine used to prevent COVID-19 caused by SARS-CoV-2. It is given to adults and children aged 6 years and older. The active substance in Spikevax is mRNA encoding the SARS-CoV-2 Spike protein. The mRNA is embedded in SM-102 lipid nanoparticles.

As Spikevax does not contain the virus, it cannot give you COVID-19.

How the vaccine works
Spikevax stimulates the body's natural defences (immune system). The vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19. Spikevax uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19.

2. What you need to know before you are given Spikevax

The vaccine must not be given if you are **allergic** to the active substance or any of the other ingredients of this vaccine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Spikevax if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine injection or after you were given Spikevax in the past.
- you have a very weak or compromised immune system
- you have ever fainted following any needle injection.

- you have a bleeding disorder
- you have a high fever or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold
- you have any serious illness
- if you have anxiety related to injections

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with Spikevax. The cases have primarily occurred within two weeks following vaccination, more often after the second dose compared to the first dose, and more often occurred in younger men.

Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Spikevax.

As with any vaccine, the primary 2-dose vaccination course of Spikevax may not fully protect all those who receive it and it is not known how long you will be protected.

Children
Spikevax is not recommended for children aged under 6 years.

Other medicines and Spikevax
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Spikevax may affect the way other medicines work, and other medicines may affect how Spikevax works.

Immunocompromised individuals
If you are immunocompromised, you may receive a third dose of Spikevax. The efficacy of Spikevax even after a third dose may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Pregnancy and breast-feeding
If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine. Spikevax can be used during pregnancy. A large amount of information from pregnant women vaccinated with Spikevax during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Spikevax can be given during breastfeeding.

Driving and using machines
Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

Spikevax contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose and, that is to say,essentially ‘sodium-free’.

3. How you will be given Spikevax

Table 1. Spikevax dosing for primary series, a third dose in severely immunocompromised and booster doses

Vaccination	Spikevax 0.2 mg/mL dispersion for injection	Spikevax 0.1 mg/mL dispersion for injection and Spikevax 50 micrograms dispersion for injection in pre-filled syringe
Primary series It is recommended to get the second dose of the same vaccine 28 days after the first dose to complete the vaccination course.	Individuals 12 years of age and older two 0.5 mL injections	Not applicable*
	Children 6 through 11 years of age two 0.25 mL injections	Children 6 through 11 years of age two 0.5 mL injections
Third dose in severely immunocompromised individuals at least 1 month after the second dose	Individuals 12 years of age and older 0.5 mL	Not applicable†
	Children 6 through 11 years of age and older 0.25 mL	Children 6 through 11 years of age and older 0.5 mL
Booster dose may be given at least 3 months after the second dose	Individuals 12 years of age and older 0.25 mL	Individuals 12 years of age and older 0.5 mL

*For primary series for individuals 12 years of age and older, the 0.2 mg/mL strength vial should be used.
†For the third dose in severely immunocompromised patients 12 years of age and older, the 0.2 mg/mL strength vial should be used.

If you miss an appointment for your primary 2nd dose of Spikevax
- If you miss an appointment, arrange another visit as soon as possible with your doctor, pharmacist or nurse.
- If you miss a scheduled injection, you may not be fully protected against COVID-19.

Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm.

After each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least **15 minutes** to monitor for signs of an allergic reaction.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Get **urgent** medical attention if you get any of the following signs and symptoms of an allergic reaction:
- feeling faint or light-headed;
- changes in your heartbeat;
- shortness of breath;
- wheezing;
- swelling of your lips, face, or throat;
- hives or rash;
- nausea or vomiting;

- stomach pain.

Talk to your doctor or nurse if you develop any other side effects. These can include:

Very common (may affect more than 1 in 10 people):
- swelling/tenderness in the underarm
- headache
- nausea
- vomiting
- muscle ache, joint aches, and stiffness
- pain or swelling at the injection site
- redness at the injection site (some of which may occur approximately 9 to 11 days after the injection)
- feeling very tired
- chills
- fever

Common (may affect up to 1 in 10 people):
- rash
- rash or hives at the injection site (some of which may occur approximately 9 to 11 days after the injection)

Uncommon (may affect up to 1 in 100 people):
- itchiness at the injection site
- dizziness
- stomach pain

Rare (may affect up to 1 in 1,000 people)
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in patients who have had facial cosmetic injections.)
- decreased sense of touch or sensation
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

Very rare (may affect up to 1 in 10,000 people)
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Frequency unknown
- severe allergic reactions with breathing difficulties (anaphylaxis)
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store Spikevax

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Information about storage, expiry, and use and handling are described in the section intended for

healthcare professionals at the end of the package leaflet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Spikevax contains

Table 2. Composition by container type

Strength	Container	Dose(s)	Composition
Spikevax 0.2 mg/mL dispersion for injection			
	Multidose vial	Maximum 10 doses of 0.5 mL each	One dose (0.5 mL) contains 100 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
		Maximum 20 doses of 0.25 mL each	One dose (0.25 mL) contains 50 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
Spikevax 0.1 mg/mL dispersion for injection and Spikevax 50 micrograms dispersion for injection in pre-filled syringe			
	Multidose vial	5 doses of 0.5 mL each	One dose (0.5 mL) contains 50 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).
	Pre-filled syringe	1 dose of 0.5 mL For single-use only.	One dose (0.5 mL) contains 50 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles).

Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2.

The other ingredients are SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.

What Spikevax looks like and contents of the pack

<u>Spikevax 0.2 mg/mL dispersion for injection</u>

Spikevax is a white to off white dispersion supplied in a 5 mL glass vial with a rubber stopper and red flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials

Spikevax 0.1 mg/mL dispersion for injection

Spikevax is a white to off white dispersion supplied in a 2.5 mL glass vial with a rubber stopper and blue flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials

Spikevax 50 micrograms dispersion for injection in pre-filled syringe

Spikevax is a white to off white dispersion supplied in a pre-filled syringe (polymeric) with plunger stopper and a tip cap (without needle).

The pre-filled syringe is packaged in 5 clear blisters containing 2 pre-filled syringes in each blister.

Pack size: 10 pre-filled syringes

Marketing Authorisation Holder
MODERNA BIOTECH SPAIN, S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

Manufacturer

For multidose vials

Rovi Pharma Industrial Services, S.A.
Paseo de Europa, 50
28703. San Sebastián de los Reyes
Madrid, Spain

Recipharm Monts
18 Rue de Montbazon
Monts, France 37260

Moderna Biotech Spain S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

For pre-filled syringe

Rovi Pharma Industrial Services, S.A.
Calle Julián Camarillo n°35
28037 Madrid Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in September 2022.

This vaccine has been given ‘conditional approval’. This means that there is more evidence to come about this vaccine.

The European Medicines Agency will review new information on this vaccine at least every year and

this leaflet will be updated as necessary.

Scan the code with a mobile device to get the package leaflet in different languages.

Or visit the URL https://www.ModernaCovid19Global.com

Detailed information on this vaccine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Storage and preparation for administration

Spikevax should be administered by a trained healthcare professional.

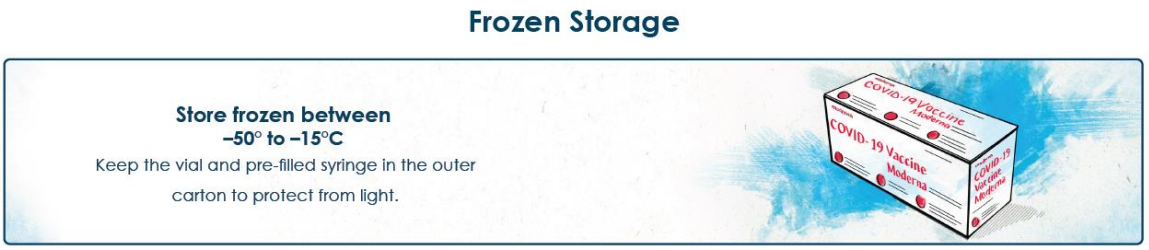
The vaccine comes ready to use once thawed.

Do not shake or dilute.

The vaccine should be inspected visually for particulate matter and discolouration prior to administration.

Spikevax is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.

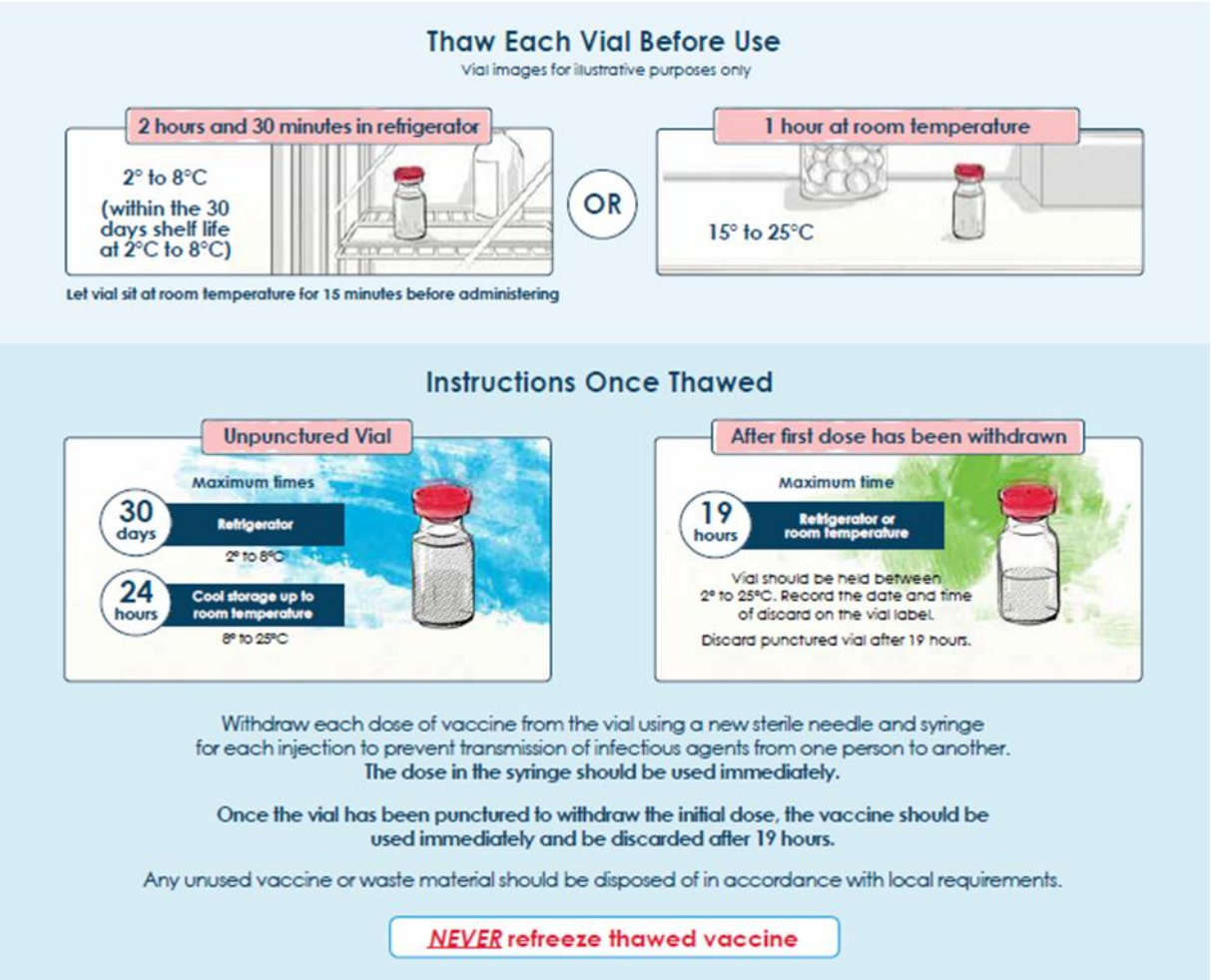
Vials and pre-filled syringes are stored frozen between -50ºC to -15ºC.



Spikevax 0.2 mg/mL dispersion for injection (multidose vials with a red flip-off cap)

Ten (10) doses (of 0.5 mL each) or a maximum of twenty (20) doses (of 0.25 mL each) can be withdrawn from each multidose vial.

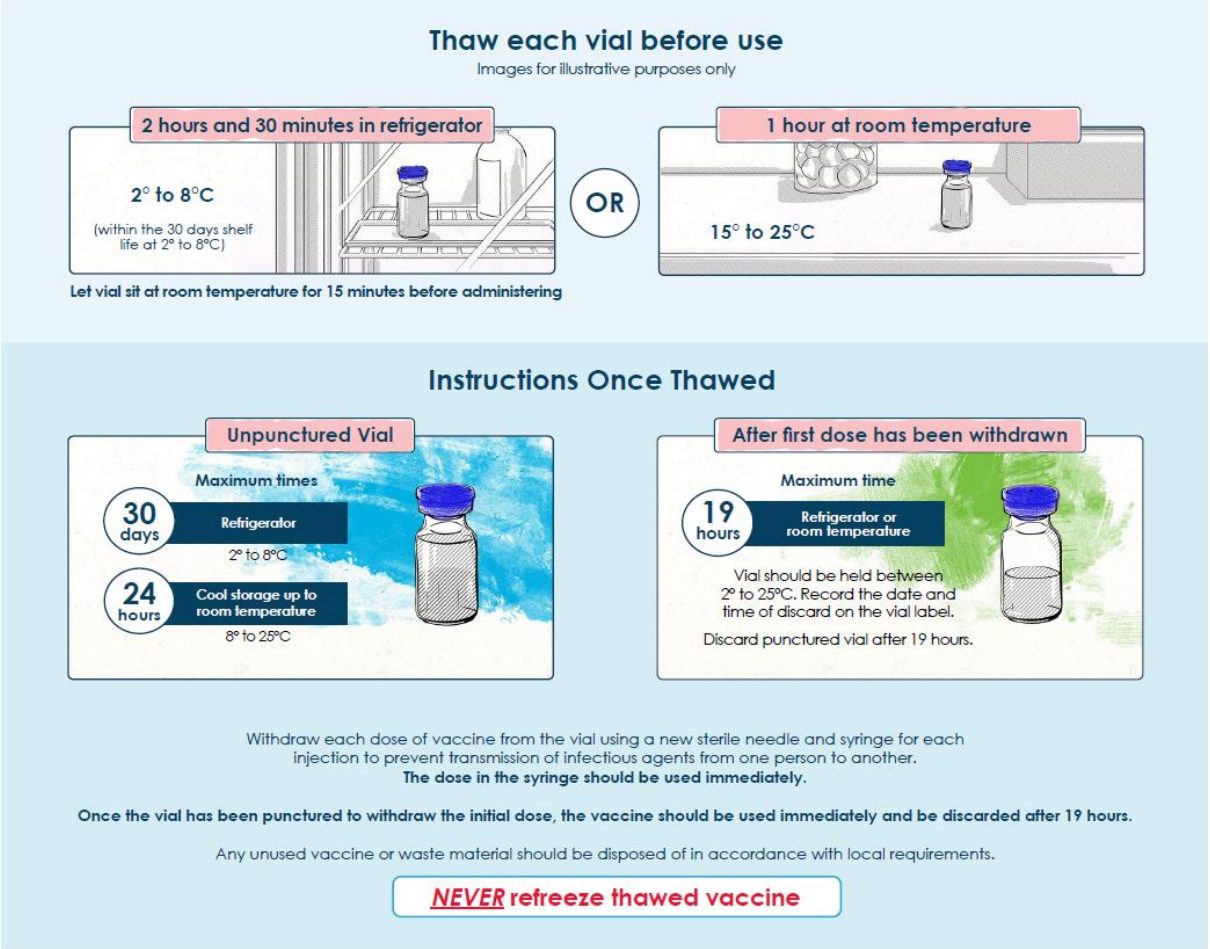
Pierce the stopper preferably at a different site each time. Do not puncture the red-cap vial more than 20 times.



<u>Spikevax 0.1 mg/mL dispersion for injection (multidose vials with a blue flip-off cap</u>

Five (5) doses (of 0.5 mL each) can be withdrawn from each multidose vial.

Pierce the stopper preferably at a different site each time.



Spikevax 50 micrograms dispersion for injection in pre-filled syringe

Do not shake or dilute the contents of the pre-filled syringe.

Each pre-filled syringe is for single use only. The vaccine comes ready to use once thawed.

One (1) dose of 0.5 mL can be administered from each pre-filled syringe.

Spikevax is supplied in a single-dose, pre-filled syringe (without needle) containing 0.5 mL (50 micrograms) mRNA and must be thawed prior to administration.

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thaw each pre-filled syringe before use following the instructions below. Syringes may be thawed in the blister packs (each blister containing 2 pre-filled syringes) or in the carton itself, either in the refrigerator or at room temperature (Table 3).

Table 3. Thawing instructions for pre-filled syringes and cartons before use

Configuration	**Thaw instructions and duration**			
	Thaw Temperature (in a refrigerator) (°C)	**Thaw Duration (minutes)**	**Thaw Temperature (at room temperature) (°C)**	**Thaw Duration (minutes)**
Pre-filled syringe in blister pack	2 – 8	55	15 – 25	45
Carton	2 – 8	155	15 – 25	140

Handling instructions for the pre-filled syringes

- Let each pre-filled syringe stand at room temperature (15°C to 25°C) for 15 minutes before administering.
- Do not shake.
- Pre-filled syringe should be inspected visually for particulate matter and discolouration prior to administration.
- Spikevax is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.
- Needles are not included in the pre-filled syringe cartons.
- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- Remove tip cap from syringe by twisting in a counter-clockwise direction.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Uncap the needle when ready for administration.
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe.
- Administer the entire dose intramuscularly.
- After thawing, do not refreeze.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Dosing and schedule

Table 4. Spikevax dosing for primary series, a third dose in severely immunocompromised and booster doses

Vaccination	**Spikevax 0.2 mg/mL dispersion for injection**	**Spikevax 0.1 mg/mL dispersion for injection and Spikevax 50 micrograms dispersion for injection in pre-filled syringe**
Primary series It is recommended to get the second dose of the same vaccine 28 days after the first dose to complete the vaccination course.	Individuals 12 years of age and older two 0.5 mL injections	Not applicable*
	Children 6 through 11 years of age two 0.25 mL injections	Children 6 through 11 years of age two 0.5 mL injections
Third dose in severely immunocompromised at least 1 month after the second dose	Individuals 12 years of age and older 0.5 mL	Not applicable†
	Children 6 through 11 years of age 0.25 mL	Children 6 through 11 years of age and older 0.5 mL
Booster dose may be given at least 3 months after the second dose	Individuals 12 years of age and older 0.25 mL	Individuals 12 years of age and older 0.5 mL

*For primary series for individuals 12 years of age and older, the 0.2 mg/mL strength vial should be used.

†For the third dose in severely immunocompromised patients 12 years of age and older, the 0.2 mg/mL strength vial should be used.

As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of an anaphylactic reaction following the administration of Spikevax.

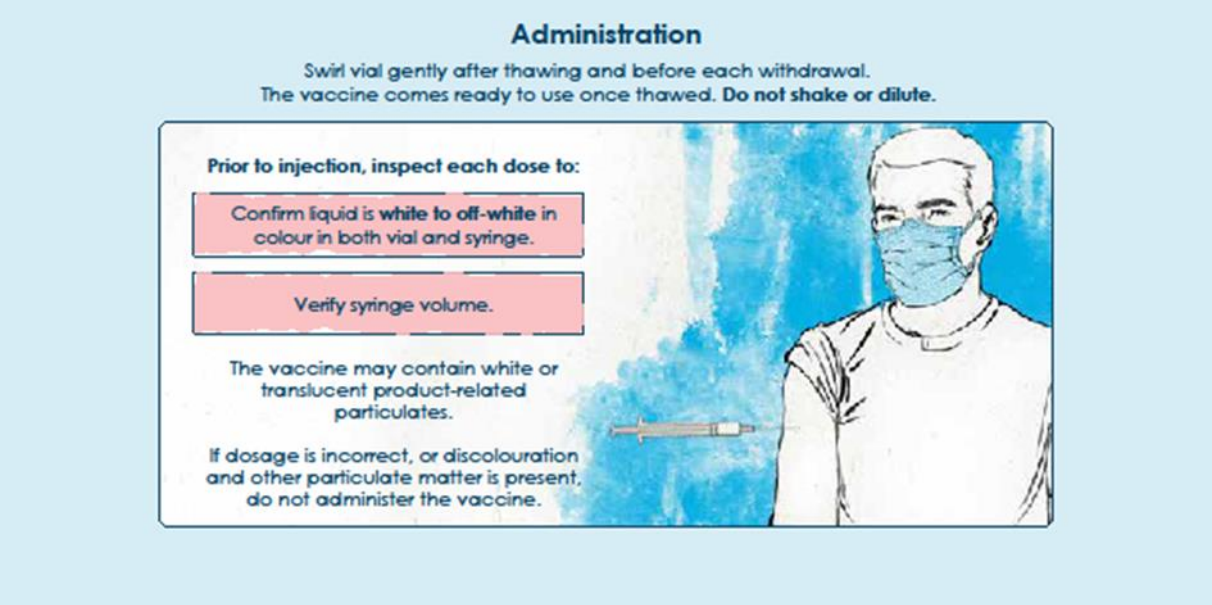
Individuals should be observed by a healthcare professional for at least 15 minutes after vaccination.

There are no data to assess the concomitant administration of Spikevax with other vaccines. Spikevax must not be mixed with other vaccines or medicinal products in the same syringe.

Administration

The vaccine must be administered intramuscularly. The preferred site is the deltoid muscle of the upper arm. Do not administer this vaccine intravascularly, subcutaneously or intradermally.

Multidose vials



Pre-filled syringes
Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner). Remove tip cap from pre-filled syringe by twisting in a counter-clockwise direction. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Uncap the needle when ready for administration. Administer the entire dose intramuscularly. Discard syringe after use. For single-use only.